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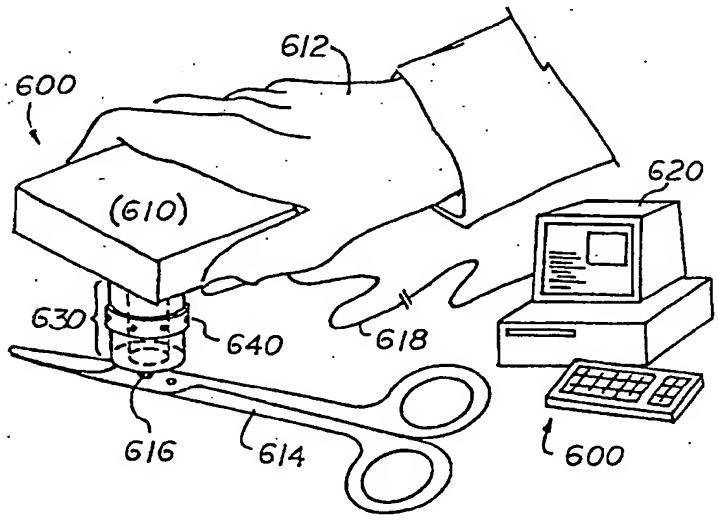

(57) Abstract

Surgical instruments (614) are marked with a symbol (120) encoding a unique numerical value associated with each instrument, this value being used as a pointer into an automated database forming part of a comprehensive inventory management system (600). The symbols on the instruments may be referenced for various purposes, including pre- and post-operative tracking, automatic flagging for routine maintenance (fig. 4) or disposal (fig. 5), packing list verification (fig. 6), and so forth. Preferably the symbols are engraved onto the surface of each instrument using a pattern of the type which may be accurately read even from the curved or non-planar surfaces typically found on such instruments.

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SURGICAL INSTRUMENT INVENTORY DATABASE MANAGEMENT SYSTEM

Field of the Invention

This invention relates generally to methods and apparatus applicable to the tracking of articles and, in particular, to a system wherein surgical instruments are marked with computer-readable symbology used to encode numerical pointers into an automated inventory management system.

Background of the Invention

Due to the current emphasis on health care reform, hospitals and related institutions are in the process of transforming their financial base from the traditional cost-plus model to a managed care system of reimbursement. As a result, cost efficiency has become of paramount importance to such organizations, mandating that all operational layers be scrutinized for any potential financial improvement.

Operating room management represents one such candidate for greater economic efficiency. In order to maintain state-of-the-art care, these facilities and the personnel involved demand increasingly sophisticated and expensive equipment and techniques to ensure the highest quality. However, little thought has historically been given to the efficiency of the business operations involved in order to support the requisite quality. In fact, surgical instruments represent a very large financial investment. A typical operating room may require an

inventory of approximately 1,500 instruments. Though varying quality and value, an average price for basic clamps used in a wide variety of procedures is $60, whereas more specialized instruments may cost much more. Using a conservative average per-instrument price of $75, such an operating room requires at least $112,500 worth of instruments in inventory. Moreover, these instruments need to be maintained not only to prolong their useful life, but also to provide quality health care. A dull pair of scissors may tear a blood vessel instead of cutting it, and a worn needle holder may allow a curved needle to spin during sewing, thus rendering it useless. Numerous other examples are possible.

The current technique used to inventory and maintain surgical instruments is simple reliance on the memory of staff in conjunction with files containing historical purchasing documents. Such a system exhibits no useful organization. It is not unusual for a hospital to spend in excess of $250,000 in a fiscal year just for the repair and replacement of damaged instruments, not including required additions to the inventory. Such non-automated tracking systems may not be used with any degree of certainty for the estimation of total inventory and, especially, may not be used to identify what has been repaired, what has been replaced, and what may be in need of maintenance.

One solution is that offered by large instrument manufacturers. In exchange for a commitment to purchase replacement instruments from a particular manufacturer, that company may bring in a team of individuals to manually

count and list the instruments in a particular hospital's inventory. However, this demands that operating rooms be unavailable for three to four days and the result is a mere snapshot of instruments available, with no system of checks and balances. Results may be entered into the manufacturer's computer, with new purchases being added as acquired. Although the hospital may inform the manufacturer when it disposes of a particular instrument, in order to remove that item from the database, maintenance problems are not addressed and the agreement between the health care facility and the manufacturer is expensive, with little or no ongoing value to the customer. Clearly there remains considerable room for improvement with regard to the tracking of surgical instruments and other such valuable articles available in large quantities.

Summary of the Invention

The present invention addresses the inventory and maintenance issues set forth above, with apparatus and methods for to track a surgical instrument throughout its useful life. Although the present invention is well suited to this application, for reasons which will become more apparent below, the apparatus and methods described herein may be used for any type of article inventorying, particularly in association with articles that may be difficult to mark or label due to the presence of non-planar surfaces, as is the case with many surgical instruments.

According to the invention, each instrument is labeled with a marker adapted to be read and decoded, even

from a curved or non-planar surface. The preferred labeling process is through laser engraving, though any other suitable marking methods may be utilized. The marker encodes a numerical code which is used as a pointer into an automated database, so that an ongoing record of that particular instrument may be easily maintained. The marker is imaged to decode the unique number, which may referenced for various purposes, including pre- and post-operative tracking, automatic flagging for routine maintenance or disposal, packing list verification, and so forth, forming part of a comprehensive surgical instrument inventory management system. Numerous tracking and flagging features are included as part of this inventory management, including diversions for maintenance, disposal, and so forth. An optional "last touch" feature automatically date stamps each interaction with an instrument by any user, automatically overwriting the previous date stamp. This allows searches to be made based upon this last touch criteria, so as to locate instruments which might be lost or in need of cycling. An instrument may be used to call up one of several distinct records associated with the instrument, with access privileges and so forth depending upon the type of operation performed. These records are displayed on the computer executing the inventory management system, and a visual indication of an instrument's physical appearance may be included in a window on the display to further ensure accuracy. In an alternative version, audio feedback may be provided upon scanning including a single or multiple different tones or synthesized messages, so that a user need not refer to the

display screen for certain tracking operations, thus saving time.

Brief Description of the Drawings

FIGURE 1 is a drawing of a surgical instrument including a marker representative of that used according to the present invention;

FIGURE 2 is an oblique drawing of a surgical instrument inventory system according to a preferred apparatus associated with the imaging of a marker;

FIGURE 3 is a printout of a screen accessed by the software of the invention, this screen exemplifying a typical record;

FIGURE 4 is a flow diagram used to indicate major steps taken by the invention during a typical post-wash/ maintenance schedule;

FIGURE 5 is a flow diagram indicating major steps taken by the invention during a typical post-wash/disposal sequence; and

FIGURE 6 is a flow diagram indicating steps carried out using the invention is association with packing station activities.

Detailed Description of the Embodiments

The present invention provides a surgical instrument inventory management system used to track instruments throughout their active service period. Each instrument is marked with a code representative of a unique numerical value. The type of marker used is preferably one which may be accurately decoded if placed on a non-planar

surface of the type typically associated with surgical instruments. For example, the marker described in co-pending application Serial No. 08/203,546 "Article Marker and Decoding Method" which is incorporated herein by reference, describes a useful candidate encoded symbol useful in conjunction with the present inventory system, though this invention is not limited to the use of any marker in particular. Although the marking may be carried out with a separate label, painting, or other alternatives, the preferred technique uses laser engraving to produce a marker which is very small in size but permanent and accurate. For example, an commercially available Electrox C.W. ND-YAG laser system may be used to etch the encoded marker onto hard surfaces such as metal and plastic. In the case of fabric or paper surfaces, the marker may be printed or applied via label as opposed to engraving.

The marker is imaged and analyzed to decode a unique number used for identification. The numerical code assigned to a particular instrument is used as a pointer into a data base, enabling the instrument to be identified as to its type and other characteristics. For example, an instrument may be identified as "scissors, Metzenbaum, 8-inch, curved" and then scanned into the database to register its unique number in association with this particular definition, which may be modified, eliminated, and so forth to reflect current usage. In addition there is a search by alias feature enabling the system to adapt to local or other nomenclature for the same instrument.

The inventory system of the present invention is typically used to track the use of surgical instruments in

a hospital setting. Such instruments typically follow a basic use cycle and usually require periodic maintenance and eventual disposal. The system tracks instruments as they pass through this basic use cycle to provide information needed to manage the inventory in terms of maintenance diversions, disposal requirements, and so forth. The system also helps to perform necessary tasks during the basic use cycle, including the preparation of packing lists which help the instrument packer determine which instruments belong in a given tray and when that tray's requirements have been fulfilled. The system further assists in comparing instrument counts in an operating room environment before and after surgery to ensure that all instruments have been accounted for.

A basic surgical instrument use cycle includes the following steps:

1) instrument washing and cleaning;

2) the packing of instruments in content-specified trays;

3) sterilization of the instruments and trays;

4) storage prior to use, as necessary;

5) delivery to the operating room;

6) instrument identification and count before surgery;

7) instrument identification and count after surgery; and

8) the return of instruments for cleaning and repacking.

In addition to this basic use cycle, instruments require

occasional and periodic maintenance, and must eventually be discarded due to irreparable damage or wear. The invention may be used to track the instruments during most or all of the steps just recited, such as just after washing, during packing, maintenance, and during surgery tallies. When combined with a full scale sweep of all instruments, the system may further identify which instruments, if any, are missing from inventory.

Figure 1 shows just one use of the present invention, in this case a pair of common straight Mayo-Hegar scissors 100 of the type used to remove wound dressings in hospital situations. As is the case with many such instruments, the scissors 100 are made of a hard and relatively inert alloy or composition such as stainless steel which contains few, if any, flat surfaces upon which to form identifying indicia. However, with the present invention, an information-bearing marker or target 120 may be etched into the instrument itself in a permanent manner, virtually on any surface large enough to contain this indicia. In Figure 1, for example, this marker is shown on one side slightly down the handle and away from the fastener 122 which holds the two halves of the scissors together, though numerous other locations are possible, as is the possibility of using more than one marker simultaneously on the same instrument or article.

Now making reference to Figure 2, there is shown an embodiment of the apparatus aspect of the present invention indicated generally at 600, including a hand-held scanning device 610 in use by an operator 612. As shown in the figure, a surgical implement 614, such as that depicted

in Figure 1, is being scanned by the implement 610 to read marker 616 previously etched on the implement and encoding a unique numerical value. The electronics within unit 610 includes a video input device, preferably a high resolution charge-coupled device (CCD) camera, which outputs a video signal along line 618 to computer 620, which performs the steps mentioned above to decode the marker and, based upon the numerical value decoded therefrom, brings up one or more records on the screen of computer 620 which represent information pertaining to the implement 614.

Each time a particular instrument is used in an operating room it may be returned to a central sterile reprocessing department of the type typically found in hospitals to be cleaned, repacked into kit form and sterilized. After initial cleaning, each instrument may be scanned again into the database to register that it has been used. Pre-programmed prompts may further be provided in the database to alert a handler when a particular instrument is due for routine maintenance intervals, or for disposal. The instrument may be diverted, refurbished and returned to inventory for use, with these and other attributes being modified and/or overwritten as required.

Figure 3 shows just one of many possible screens associated with numerous records which may be created as part of the surgical instrument database inventory. The picture of the screen in Figure 3 is that part of the program used to enter a new, coded instrument into the database, the type of instrument in this case being scissors. Fields are provided for aliases and descriptions of the instrument and, in the bottom portion, various

commands may be entered either with a keyboard or through the use of a cursor.

Figure 4 illustrates a post-wash/maintenance schedule. After an instrument is washed it may be scanned into the database using the invention, registering one use. At this point a "last touch" date stamp may also be applied. If the instrument is not due for maintenance it may be delivered to the packing station at this point, however, if due for maintenance and the alert is not overwritten, it may be diverted for maintenance through system administration. Upon return, it is again washed and scanned into the database registering one use, and sent to the packing station.

Figure 5 depicts a typical post-wash/disposal sequence. As with the maintenance sequence, after washing and scanning, the instrument may be sent directly to the packing station. However, if a disposal alert is present and not overwritten the instrument will be diverted for disposal through system administration and if the disposal cycle is approved, the instrument will be discarded, changing the status to "disposed."

Figure 6 indicates functions which might be performed during a typical packing station routine. Typically, clean instruments are delivered to such packing stations with packers receiving a daily list of the packs required for upcoming operative cases. In such circumstances, the packer may use the invention to call up a list on the database of the contents required for a particular doctor and a particular case. Alternatively, a generic packing may be utilized which may be used in part

or in its entirety for any number of doctors, since any such combination is possible through database identification. The pack content list or "preference cards" may preferably be specific to each hospital using the system.

In operation, a list of instruments and sterile supplies required for a particular case will appear on a computer screen forming part of the present invention. The instruments already in the pack may then be scanned, with any discrepancies being flagged, at which point the packer has the option to correct the contents or override in the event that some variation is required for a particular case. If a packer has a question about the type of a particular instrument, that instrument may be scanned and its definition, description, alias names and an optional picture may be provided in an instrument catalog section of the database.

When finished with a particular packing operation, a unique number or tray ID may be assigned to the assembled pack. If desired, a staff member loading the sterilizer may note the tray ID so that permanent sterilization histories may be maintained on each instrument and on a case-by-case basis for later reference by oversight groups such as the Joint Commission On Accreditation Of Hospitals Organization (JCAHO), internal quality assurance committees, or risk management departments.

When used in conjunction with hand-held scanning, the invention enables operating room personnel to perform on-site pre- and post-operative counts of instruments

automatically and electronically. This is in contrast to prior-art manual techniques, which may take roughly 20 minutes per case. Using a conservative estimate of $50 per minute for the cost of all nursing personnel, surgeons, anesthesiologists, administrative support, and fixed overhead, such on-demand electronic accounting may be performed twice as fast as prior-art techniques, resulting in a potential savings of $500 per operative situation.

In addition to database management, the present invention provides apparatus and methods for marking and reading encoded articles, particularly in situations where such instruments represent a very large financial investment and must be accurately tracked for reasons of efficiency, required maintenance, and potential liability. Additionally, the invention may be used in hospitals or the medical care field for patient identification. In fact, the invention may be used in any situation where it is important or essential to keep track of numerous items, particularly expensive items or items which are especially difficult to permanently label due to their small size or a preponderance of hard or curved surfaces. As other examples outside the medical profession, the invention may be used in conjunction with identifying small machine or electronic components for commercial, industrial or military purposes, or for the marking of controlled articles, such as weaponry, ammunition, and so forth.

Having thus described our invention, we claim:

1. A method of tracking surgical instruments, comprising the steps of:

labeling a plurality of surgical instruments with an encoded symbol, each symbol being representative of a unique numerical value;

imaging the symbol on each instrument;

decoding the symbol with a programmed computer to determine the numerical value associated therewith;

creating a database in the computer, the database including a record associated with each instrument referenceable by the numerical value for that instrument;

reading the symbol of each instrument in a group of instruments assembled for a desired use to ensure that each instrument belongs in the group; and

reading the symbol of each instrument after the use to ensure that all instruments of the group are accounted for.

2. The method of claim 1, including the step of displaying information relating to the record of a particular instrument upon the decoding of its symbol.

3. The method of claim 2, including the steps of:

obtaining a data representative of the physical representation of an instrument, including the data in the record for that instrument; and

displaying the physical representation on the screen as part of the step of displaying information relating to the record of a particular instrument.

4. The method of claim 1, the record associated with each instrument including an assignable instrument name.

5. The method of claim 1, further including the steps of:

generating a packing list associated with the group of instruments required for the desired use; and

assigning an identification code to the packing list.

6. The method of claim 1, the step of labeling a plurality of surgical instruments with an encoded symbol including the step of permanently engraving the symbol.

7. A surgical instrument tracking system, comprising:

means for marking each of a plurality of surgical instruments with an encoded symbol, each symbol representing a unique numerical value;

means to image a symbol on an instrument and deliver a signal representative of the numerical value to a programmed computer including an associated display device; and

an inventory management system resident in the programmed computer including a record associated with each instrument, the numerical values being used as pointers into a database, the inventory management system being operative to display information associated with the record for a particular instrument upon imaging the symbol for

that instrument.

8. The system of claim 7, the means to image a symbol on an instrument including a hand-held scanner.

9. The system of claim 7, further including means to uniformly illuminate the marker on the article to improve imaging accuracy.

10. A surgical instrument tracking method, comprising the steps of:

marking each instrument with an encoded symbol storing a unique number;

storing in an automated database information relating to the instrument referencable by its unique number;

imaging a portion of the instrument containing the symbol so as to determine the unique number; and

using the number as a reference into the database to recall the information relating to the instrument.

AMENDED CLAIMS
[received by the International Bureau
on 05 September 1995 (05.09.95);
original claims 9 and 10 amended;
remaining claims unchanged (1 page)]

that instrument.

8. The system of claim 7, the means to image a symbol on an instrument including a hand-held scanner.

9. The system of claim 7, further including means to uniformly illuminate the symbol on a particular instrument to improve imaging accuracy.

10. A surgical instrument tracking method, comprising the steps of:

marking each of a plurality of surgical instruments with an encoded symbol representative of a unique number;

storing in an automated database information relating to each instrument referenceable by its unique number;

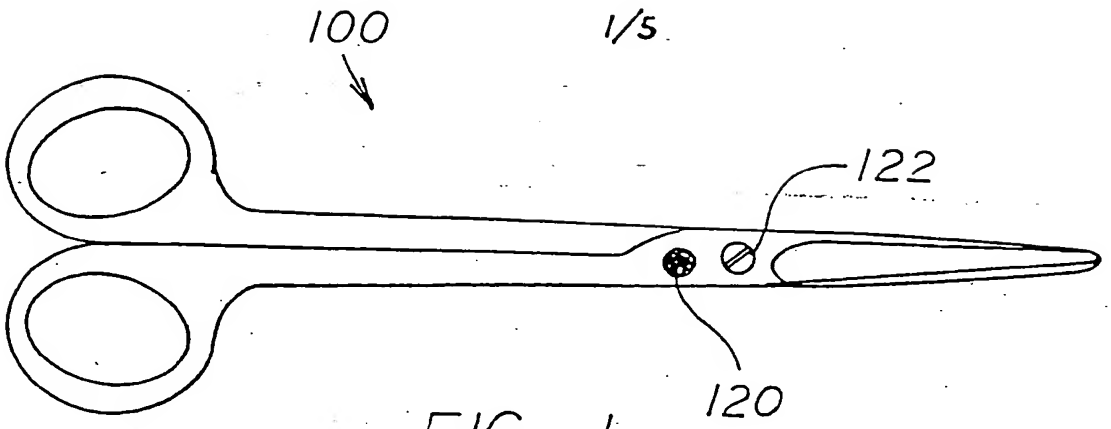
imaging a portion of the instrument containing the symbol so as to determine the unique number; and

using the number as a reference into the database to recall the information relating to the instrument.

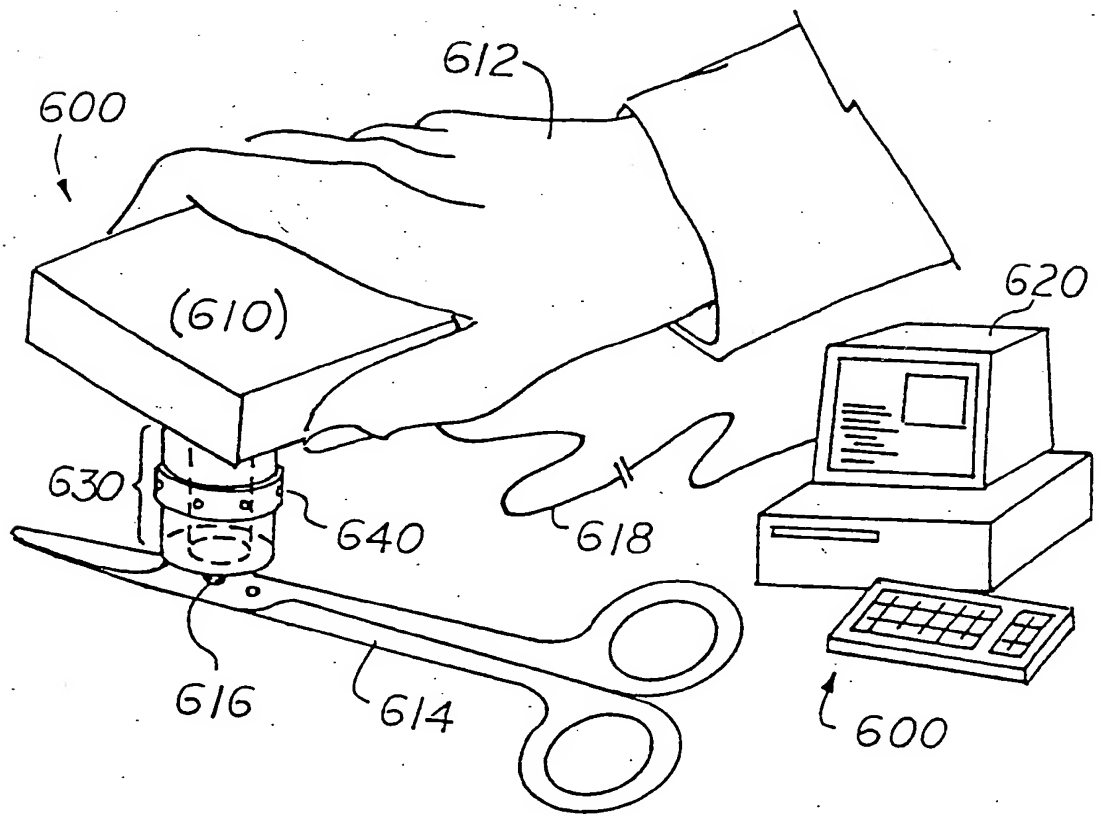
STATEMENT UNDER ARTICLE 19

It is desired to note that the claimed subject matter is novel and can be shown to comprise an inventive step, evidence of which Applicant reserves the right to make of record in due course of the prosecution.

The above amendment does not go beyond the disclosure in the international application as filed.



FIG— 1



FIG—2

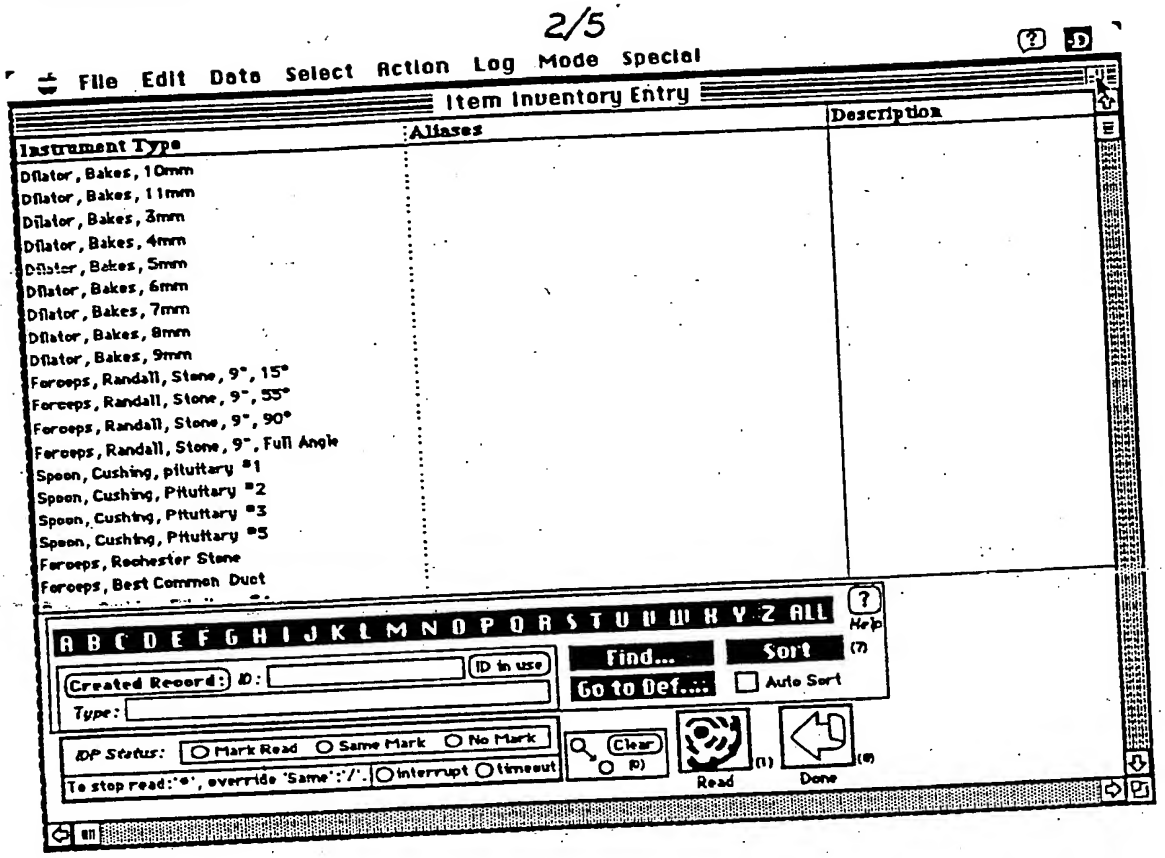


FIG 3

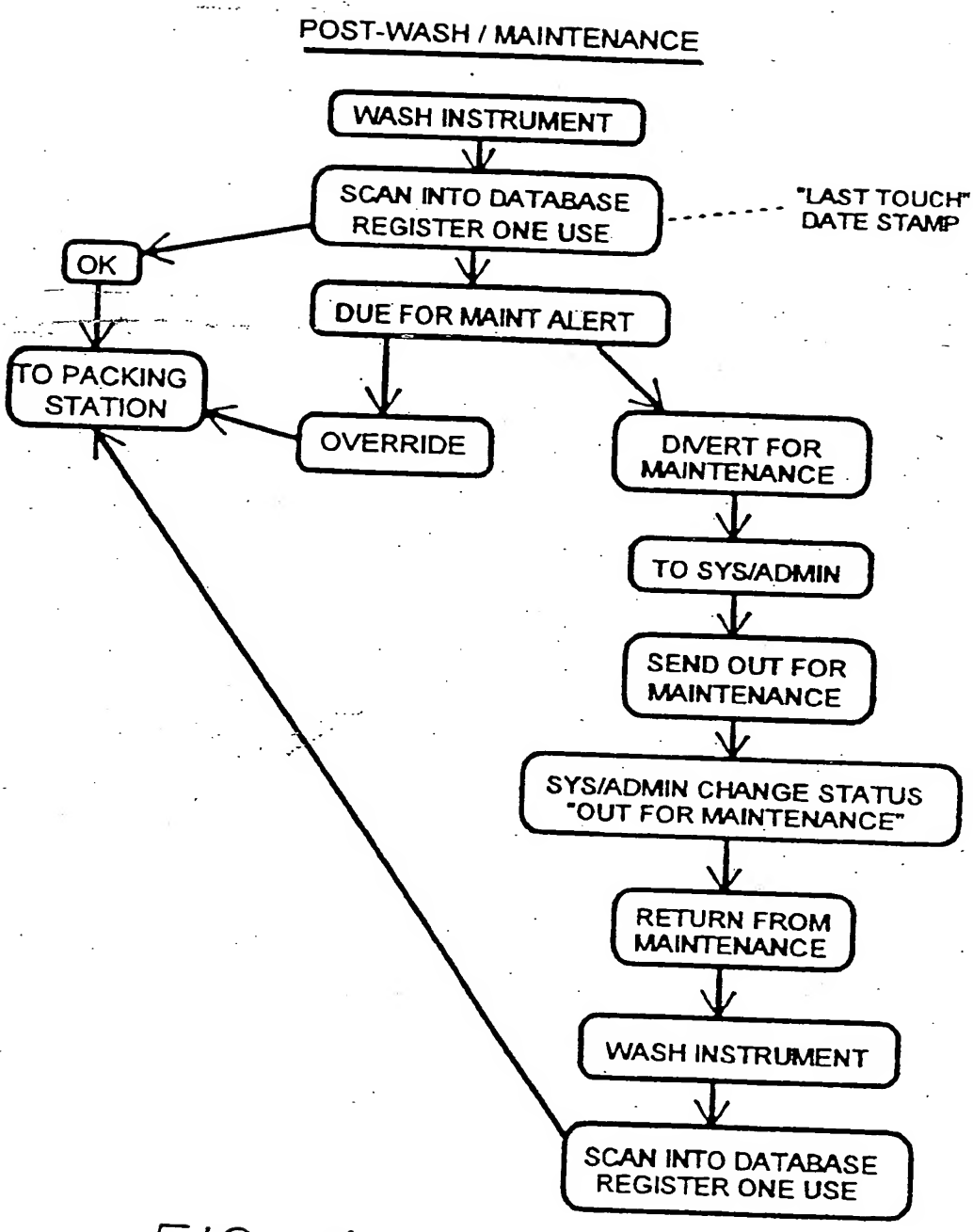


FIG 4

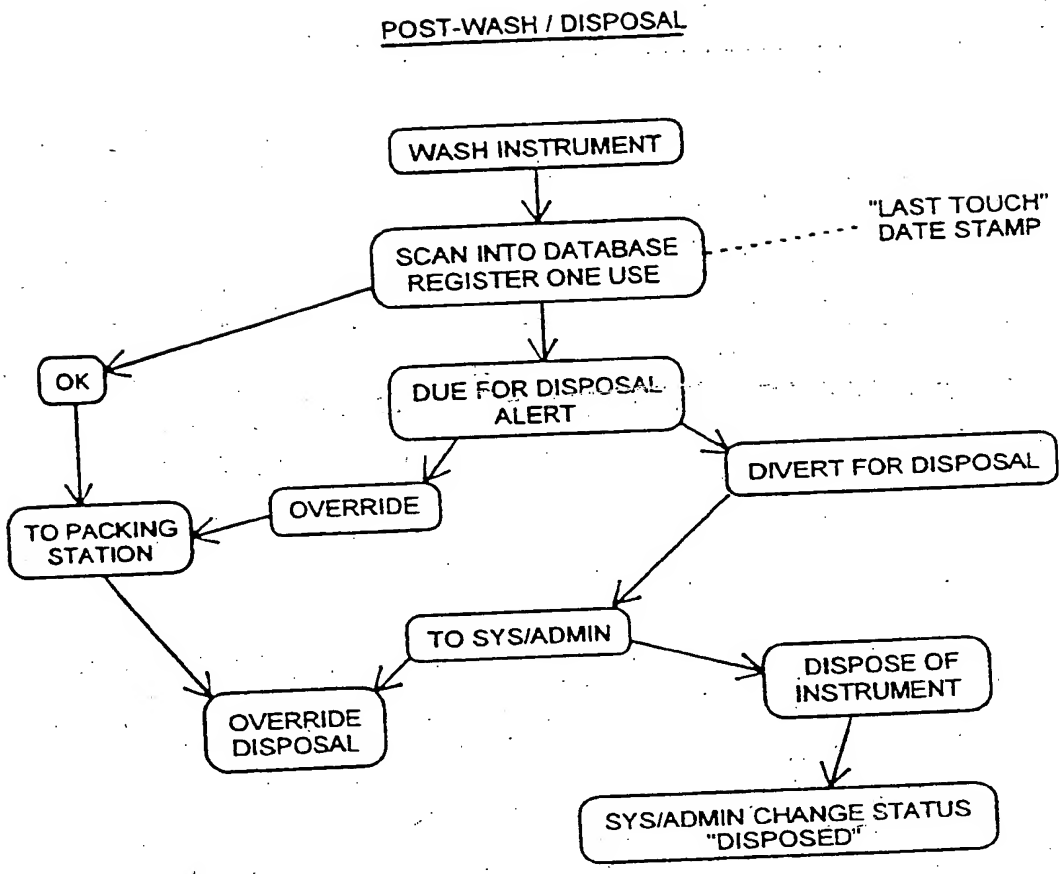
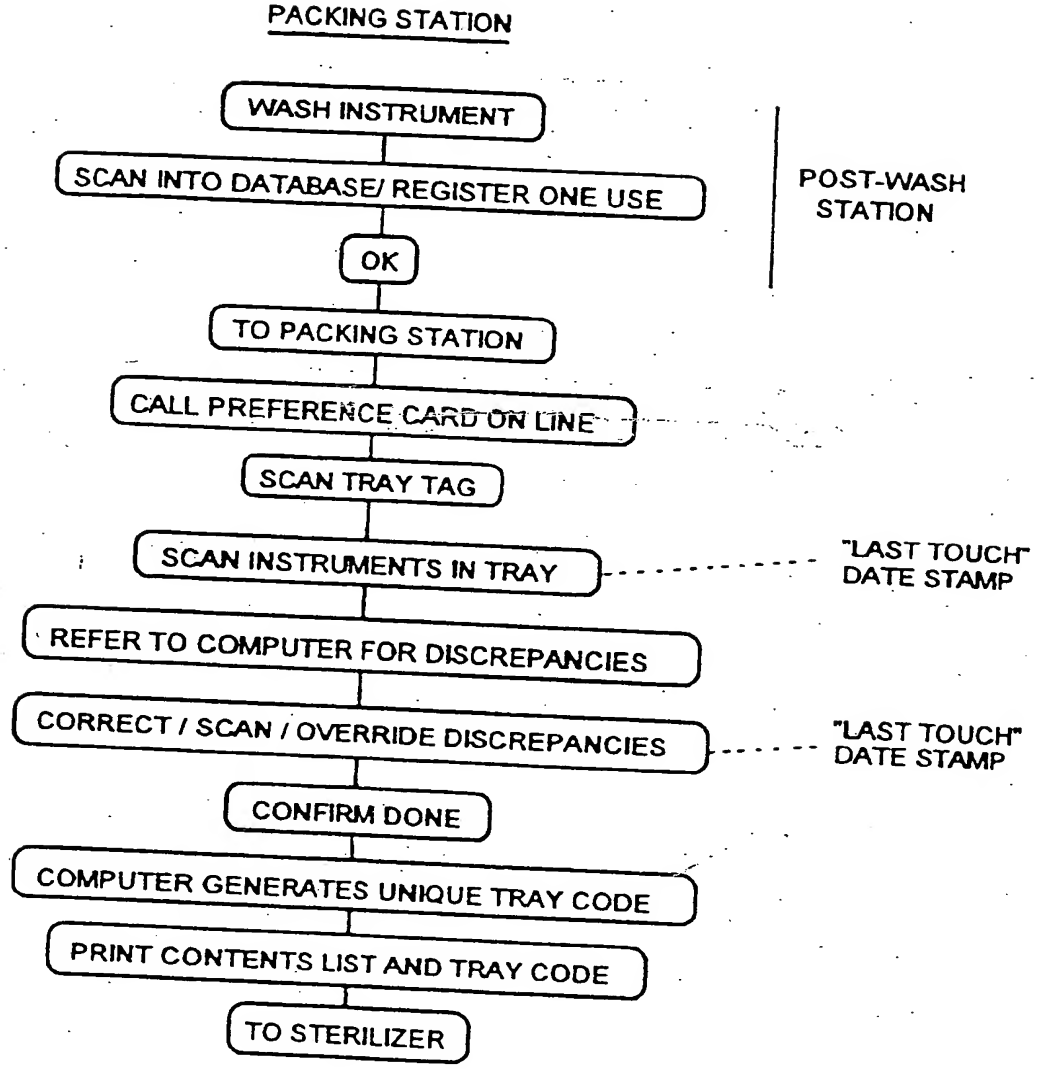


FIG 5



FIG— 6

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US95/03885

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :G06F 15/00
US CL :364/403; 235/462
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 40/913; 206/570; 235/375, 385, 462, 454; 364/403, 413.01, 478, 479; 433/77, 79, 141, 229; 434/219, 262, 365, 367

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

DIALOG:
surgical instrument, dental instrument, bar code, code, symbol, inventory, list, image, picture

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US, A, 4,882,867 (LINDEN) 28 NOVEMBER 1989 see entire document	1-10
Y	US, A, 4,900,252 (LIEFKE, et al.) 13 FEBRUARY 1990 see col. 5, lines 17-43	1-10
A	US, A, 4,943,939 (HOOVER) 24 JULY 1990 see entire document	1-10
Y	US, A, 4,988,295 (KLINE) 29 JANUARY 1991 see entire document	1-10
Y	US, A, 5,038,283 (CAVENEY) 06 AUGUST 1991 see col. 2, lines 58-68	1-10
P,Y	US, A, 5,374,813 (SHIPP) 20 DECEMBER 1994 see col. 4, lines 11-20	1-10

[X] Further documents are listed in the continuation of Box C. [ ] See patent family annex.

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Date of the actual completion of the international search 13 MAY 1995	Date of mailing of the international search report 10 JUL 1995
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer GAIL O. HAYES Telephone No. (703) 305-3800

Form PCT/ISA/210 (second sheet)(July 1992)*

INTERNATIONAL SEARCH REPORT

International application No.
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C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y,P	Dentist's Checklist & Tray Setup System; Friedman, et al.; On the Mark Computer Software Co.; Release Date: 10/1988; Dialog: File 278, Acc# 0013366; see entire document	1-10